K083679

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SEP 11 2009

510(k) Summary

Submitter
UroVal, Inc.
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Date Prepared
Sept 8, 2009

Name of Device

Common Name:	EMG System
Proprietary Name:	UroVal BRS System
Classification Name:	Electromyography, Diagnostic
Regulation:	21 CFR 890.1375
Class:	Class II
Product Code:	IKN

Predicate Devices
The UroVal BRS System is substantially equivalent in intended use, function and basic composition to the currently marketed MLS MA-300 System (K000220), and The Prometheus Group CTS 2000 System (K001515).

Device Description
The UroVal BRS System is used to record and display electromyogram (EMG) signals. In addition, the BRS System will determine latency time intervals of the bulbocavernous reflex (BCR). The UroVal BRS System also has report generation capabilities.

The UroVal BRS System uses a probe, with a single use disposable tip to evoke a BCR response, and activate recording and timing of EMG signals.

The UroVal BRS System uses pregelled surface electrodes to monitor the muscle activity.

Intended Use
To acquire EMG signals for display and analysis by, or under the direction of a health care professional, to assess neurogenic sacral dysfunction such as urinary incontinence and fecal incontinence.

Technological Characteristics
The UroVal BRS System has similar technological characteristics to the currently marketed predicate devices listed above. The UroVal BRS System meets standards:

ISO 10993-1	(2003)	Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing
ISO 10993-5	(1999)	Biological Evaluation of Medical Devices: Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	(2002)	Biological Evaluation of Medical Devices: Part 10: Tests for irritation and delayed-type hypersensitivity
IEC 60601-1	(2006)	Medical Electrical Equipment –Part 1: General Requirements for basic safety and essential performance
IEC 60601-1-2	(2001)	Medical Electrical Equipment – Part 1-2: General Requirements for Safety: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
IEC 60601-1-4	(2000)	Medical Electrical Equipment – Part 1-4: General Requirements for Safety: Collateral Standard: Programmable electrical medical systems

Performance Data (non-clinical or clinical)

The UroVal BRS System performance was compared to the CTS 2000 in a clinical trial, and is substantially equivalent to the predicate devices based on the device characteristics, descriptive data, compliance with standards, and indications for use.

Conclusion

The technological characteristics and performance data for the UroVal BRS System demonstrates it performs safely and effectively, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 11 2009

UroVal
% RCRI, Inc.
Ms. Sharon Iverson
Regulatory Project Director
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416

Re: K083679
Trade Name: UroVal BRS System
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic electromyograph
Regulatory Class: II
Product Code: IKN
Dated: September 3, 2009
Received: September 4, 2009

Dear Ms. Iverson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K083679

Device Name: UroVal BRS System

Indications For Use: To acquire EMG signals for display and analysis by, or under the direction of a health care professional, to assess neurogenic sacral dysfunction such as urinary incontinence and fecal incontinence.

Prescription Use X AND/OR Over-The-Counter Use _____
(21 CFR 801.Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083679